

REMARKS

I. Status of the Claims

Prior to the Action, claims 21-54 were pending and have been examined without entry of a Restriction Requirement. Presently, independent claims 21, 22, 24, 25, 26, and 53, are amended, and, new dependent claims 55-56 have been added.

Claims 21-56 are therefore in the case. According to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

Support for the Claims

Currently amended claim 22 and new claims 55-56 that are dependent on the currently amended claim 22, are drawn to the C-phosphonate analogues of phosphoinositides; support for phosphonate analogues of phosphoinositides can be found throughout the specification, and, in particular at page 4 (lines 23-28) read in conjunction with the structure on page 5 (lines 1-9), and the text on page 9 (lines 10-11). Claim 22 has been amended by (1) deleting the original structure with the chemically mandatory “two CH₂ groups attached to the phosphorus” and (2) substituting therefor: (i) the normal cellular phosphoinositide structure with just one CH₂ group attached to the phosphorus, and, (ii) the stipulation that in the said C-phosphonate compounds, an O-P bond of phosphate moiety in the cellular phosphoinositide structure is replaced by a C-P bond. Support for this amended claim 22 is found in particular on page 4 (lines 23-28) read in conjunction with the structure on page 5 (lines 1-9), and the text at page 9 (lines 10-11) of the specification. Claim 25 has been currently amended by deleting the numbers 2, 3, 4, and 5 as being superfluous legends to the respective structures.

New claims 55-56 are dependent on the currently amended claim 22; claim 55 stipulates that the O-P bond link to glycerol in the phosphoinositide structure is replaced by a C-P bond, whereas claim 56 stipulates that the O-P bond link to inositol in phosphoinositide structure is replaced by a C-P bond. Support for claims 55 and 56 is found in particular on page 4 (lines 23-28) read in conjunction with the structure on page 5 (lines 1-9), and the text on page 9 (lines 10-11) of the specification.

Claims 21, 24, 26, and 53 have been amended to improve clarity by deleting in each claim the first phrase “derivative thereof” and replacing it with “derivative of ceramide residue”, and, by deleting the second phrase “derivative thereof” and replacing it with “derivative of sphingosine residue.” Claim 24 has been amended also by deleting the structure numbers **2, 3, 4, and 5**, as being superfluous legends to the respective structures.

II. 112 First Paragraph Rejections (New Matter)

The Action states that “Claims 22, 23, 25, 27-29, 31, 34, 35, 38, 39, 42-52, and 54 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention. The particular and primary basis for the foregoing conclusion, as alleged by the Action, is that the structure appearing in the amendment filed 1/24/02 is inconsistent with that of disclosure (page 5, line 1), because, as an example, the graphical structure in independent claim 22 is drawn with two CH₂ groups attached to the phosphorous instead of just one CH₂ group attached to the phosphorous in the structure at page 5, line 1 of the disclosure (Substitute Specification). Based on foregoing, the Action alleges that the independent claims 22, 25, 27, and 54, and all claims depending on these (claims 23, 28, 29, 31, 34, 35, 38, 39, 42-52, and 54) constitute new matter.

Applicant respectfully traverses and submits as follows:

The chemical name C-phosphonate used in claim 22 is synonymous with phosphonate used in the specification, and the two names are used synonymously in the relevant chemical arts. The present invention pertains to phosphoinositides as well as novel analogues that include but are not limited to phosphonate analogues of phosphoinositides. Support for this is found throughout the Specification, and in particular on page 4, lines 23-28. It is well known in the relevant chemical art that the phosphate structure has O-P bonds and that the analogous phosphonate structure has a C-P bond in place of the said O-P bond; this formalism is overtly disclosed in the specification, for example at page 9, lines 10-11. The Action relies on the structure at page 5, line 1 of the disclosure as the basis for rejection under 35 U.S.C. § 112, first

paragraph. The Applicant respectfully points out that the said structure is preceded on page 4 by lines 27-29, and qualified by the statement “The novel analogues are closely related to the cellular phosphoinositides shown in the generalized structure below.” The said structure is graphical representation only of the cellular phosphoinositide types, whereas “the corresponding thiophosphates, and phosphonates, and the radyl and sphingo type inositolphospholipids” analogues disclosed at least on page 4, lines 26-27 of the specification, are defined by the respective structural features that are well known characteristics of thiophosphate, phosphonate, radyl and sphingo residues. Accordingly, the structures in claims 22, 25, 27, and 54 are each a graphical structural representation of the subject matter that is clearly recited in the aforementioned combination of structural and text forms in the specification. Thus, claims 22, 25, 27, and 54 do not contain new matter, and accordingly, their dependent claims 23, 28, 29, 31, 34, 35, 38, 39, and 42-52 do not contain new matter. Nonetheless, in the interest of progressing the present case to allowance efficiently, claim 22 has been amended as described above, and dependent claims 55-56 (dependent on claim 22) have been added that define alternative locations of the C-P bonds linking either to the glycerol or to the inositol residues. As discussed above, these alternative links are fully supported by the text at page 9, lines 10-11 of the specification.

It will thus be seen that the claims have been currently amended to better represent the original description of the invention in the specification and using terms that would be understood to have been disclosed in the original specification, and not to exclude a range of equivalents from the claims. Thus, all rejections under 35 U.S.C. § 112, first paragraph are overcome and should be withdrawn.

III. 112 Second Paragraph Rejections

Claims 21, 24, 26, and 53 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner helpfully guides Applicant to clarify what compounds are encompassed by Applicant's phrase "derivative thereof" in order that one may readily ascertain what is being claimed. Although Applicant respectfully traverses, and submits that the claims as originally written were sufficiently definite when read, as they must be, in light of the text and structures in the specification and figures, and the applicable chemical art. Specifically, the applicant submits that the meaning and scope of the phrase "derivative thereof" is well understood in the general chemical arts, as well as by practitioners of the related art as applied to the ceramide or sphingosine residues. Ceramide residues contain derivatizable unsaturation and free hydroxyl groups, and the sphingosine residues contain unsaturation, free hydroxyl and amino groups. As is generally understood, derivatization is effected by addition, e.g., of hydrogen, epoxide, imine or hydroxyl(s), to the unsaturated bond(s), or by replacement or substitution, either of the hydrogen in the alcohol or amino groups, or of the complete hydroxyl or amino groups; examples of facile derivatization include but are not limited to acylation to form acyl ester or amide, or substitution to form deoxy-halo, -azide, and -thiol derivatives. Nonetheless, to address the Examiner's concerns and in the interests of progressing the present case to allowance efficiently, the claims have been clarified to address the concerns expressed solely under § 112, second paragraph. Specifically, in each of amended claims 21, 24, 26, and 53, the phrases "Ceramide residue or derivative thereof, or Sphingosine residue or derivative thereof" have been replaced by the equivalent but clearer phrase "Ceramide residue or derivative of a ceramide residue", or "Sphingosine residue or derivative of a sphingosine residue."

It will thus be seen that the claims have been revised to better define the invention in terms that more particularly point out and distinctly claim the unique features of the invention, and not to exclude a range of equivalents from the claims.

The rejections under 35 U.S.C. § 112, second paragraph are thus overcome and should be withdrawn.

IV. Double Patenting Rejections

The Action next rejects claims 22, 23, 25, 27-29, 31, 34, 35, 36-52, and 54 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims in Applicant's earlier U.S. Patent No. 6,376,697. The Action, on page 4 last four lines at bottom of page, makes the observation that the instant invention includes claims wherein the variable T is defined as S (sulfur) as distinct from ³⁵S.

The Applicant submits that the variable T = sulfur provides a graphical structural representation, conforming to the practice in the relevant chemical art, of the thiophosphate analogues of the phosphoinositides. These thiophosphate analogues of the phosphoinositides are supported in the specification, in particular at page 4 line 25, page 5 line 15, and page 9 line 10. Thus it will be seen that claims wherein the variable T = S (sulfur) do not constitute new matter.

Applicant notes that any concerns regarding new matter, expressed in the Action, have been addressed in the previous sections and the preceding paragraph. In response to the obviousness-type double patenting rejection, Applicant presently submits a Terminal Disclaimer and the required small entity fee. The obviousness-type double patenting rejection is thus overcome and should be withdrawn.

V. Claim Objections

Claims 30, 32, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. The examiner's guidance is appreciated. The applicant submits that the objections to the base claim 21 have been overcome in the currently amended claim 21 as submitted. Therefore, the objection to dependent claims 30, 32, and 33 should be withdrawn.

V. Formalities

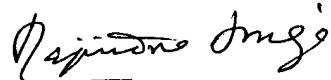
The inventor, Rajindra Aneja, Ph.D., is also the Director of the Assignee, Nutrimed Biotech. An Assignment is of record at reel 010115, frame 0507. The inventor/Applicant is now acting *pro se*. Please direct any correspondence to:

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VII. Conclusion

In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such action is respectfully requested. Should Examiner Jones have any questions or comments, a telephone call to the undersigned Applicant is earnestly solicited.

Respectfully submitted,



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Date: May 17, 2005